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|---|--------------|----------------------|---------------------|------------------|
| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/676,154 | 09/29/2003 | John Landers | M0656.70098US00 | 7775 |
| 23628 | 7590 | 04/28/2011 | EXAMINER | |
| WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206 | | | SALMON, KATHERINE D | |
| ART UNIT | PAPER NUMBER | | | |
| 1634 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 04/28/2011 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|---------------------------------------|
| Office Action Summary | Application No. 10/676,154 | Applicant(s) LANDERS ET AL. |
| | Examiner KATHERINE SALMON | Art Unit 1634 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 14 February 2011.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 151-156 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 151-156 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsman's Patent Drawing Review (PTO-442)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____

5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

1. This action is in response to papers filed 2/14/2011.
2. Claims 151-156 are pending.
3. The following rejections are newly applied. It is noted that although in the previous office action it was indicated that RCG containing less than 1% appeared to be novel over the prior art, based upon the indefiniteness of this calculation presented below rejections have been newly applied. In particularly it is not clear how the RCG percentage is calculated and as such it is not clear the metes and bounds of the claims.
4. This action is NONFINAL.

Withdrawn Rejections

5. The 35 USC 103(a) rejections made in the previous office action are withdrawn based upon the cancellation of the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 151-156 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 151-156 are indefinite over the phrase "preparing a RCG using at least one PCR primer wherein the RCG contains less than 1% (0.05%) of genomic material

present in a whole genome:. It is unclear how the calculation of the genomic material present is determined because this percentage appears to be a function of the experimental conditions and hence the metes and bounds of the claims are not clear.

In particular the specification points to the fact that RCG may be derived using a DOP PCR with a primer having a Tag-Nx-Target motif wherein the target can include fewer or more than 7 nucleotides and X is an integer from 0 to 9 (p. 5 lines 10-25). The specification further teaches that the RCG can include a plurality of fragments wherein 1% or 0.05% of the native genome is represented (p. 18 lines 12-20). The specification presents a specific probe (e.g. SEQ ID No. 4) with a 3' end of that is 8bp specific (p. 13 lines 22), however, the specification does not indicate which percentage of RCG will be obtained by using this sequence. Although the specification provides an example of a specific probe, the specification has not provided the calculation needed to determine which prepared RCGs would represent less than 1% or less than 0.05% percent of the genome. Cheung et al. (Proceedings National Academy Science 1996 Vol 93 p. 14676 cited previously on the PTO-892) appears to indicate that an estimate of about one million DOP-PCR fragments generated from the entire human genome (p. 14676 2nd column 1st paragraph). Cheung et al. asserts that since the average size is 500 bp that there is a one in six chance of being included in the DOP-PCR product. This appears to indicate that the RCG represented by the DOP-PCR used by Cheung is about 16% of the total genome. However, Cheung later states that if priming at the initial low temperature annealing is occurring because of all 6 specific base pairs on the 3' end, that there is an expectation to have amplified only about 1 of every 10 200 to 10000 bp

(p 14678 2nd column last paragraph). Therefore if the entire human genome (3×10^9) is broken up into 200 bp fragments there were be 15,000,000 fragments. As such the DOP amplification would amplify 1500000 of these fragments (10%). This calculation is vastly different from the 16% initially discussed on p. 14676. Further, Cheung et al. indicates that the composition of the 3' fragment (e.g. the number of A, T, C, or Gs) would effect the determination because different bases have a different estimate of occurrence (p. 14678 last paragraph). Further, Cheung points to the fact that subsequent PCR amplification at higher annealing temperatures makes use of the specificity at the 5' end and that Taq DNA polymerase is limiting (p. 14678 last paragraph to 14679 1st paragraph). As such it is unclear how to determine the RCG production based upon the guidance in Cheung as it appears that the composition of the 3' position, the annealing temperature, and Taq polymerase all are involved and as such it unclear what calculation is used to determine the percentage of RCG and therefore which randomly amplified primers would encompass the production of such a percentage.

Fisher et al. (Nucleic Acids Research 1996 Vol. 24 p. 4369) further illustrates the indefiniteness of the determination of the percent of RCG. Fisher et al. teaches that PCR conditions are crucial when using degenerate primers which anchors (p. 4369 last paragraph). Fisher et al. teaches that excessive stringency produces no amplicons whereas low stringency will permit slippage of the primer (p. 4369 last paragraph). As such Fisher et al. indicates that the amount of amplicons produces (e.g. the RCG) is in some way dependent upon the PCR amplification conditions. As such it is not clear if a

DOP Primer used in one amplification constraint would produce the same percentage of RCG in another amplification constraint. As such it is not clear which primers would be encompassed in the limitation of preparing an RCG which contains less than 1% or less than 0.05% of the whole genome.

Even in post filing art there does not appear to be a particular calculation to determine which primers will produce RCGs containing less than 1% or 0.05% of the whole genome. Osman et al. (Plant Physiology March 2003 Vol 131 p. 1294) a method of reducing complexity using DOP PCR primers similar to the ones described in the instant specification. Osman et al. teaches that the length of the specific sequence at the 3' end of the primer should decrease the complexity, but also reducing the annealing temperature will reduce the size of the PCR products (p. 1296 1st column last paragraph to 2nd column 1st paragraph). Table II indicates the total sequences amplified for each DOP primer with a unique 3' specific end. DOP Primer 2, 3, 4 are composed of different nucleotides but are all 11 mer in length. These primers produce a different total number of sequences (for example DOP 2 produced 25 sequences versus DOP 3 which produced 54 sequences). As such the post filing art indicates that it is not just the length of the DOP primer that is used to calculate the percentage of RCG, as Osman et al. shows that two DOP primers with the same 3' length will produce a different number of total sequences.

As such it appears that there are many components to determine the complexity reduction of a particular random primer. Not only does the length of the 3' specific region effect the percentage of RCG produce, but also the composition of the specific

region (e.g. the number of bases that are A, G, C, and T), the amount of TAQ polymerase used in the reaction, and the annealing temperature. As such it is unclear the metes and bonds of the claims. In particular, as it is not clear how the percentage of RCG is calculated based upon the prior art disclosure and the specification, it is not clear which primers would produce the required percentage of genomic material. Rather, it is not clear is the RCG calculation is based upon some probably frequency using the size of the specific section of the probe and the composition of the probe or an absolute calculation which further requires an analysis of the reaction constraints.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 151-153, 155-156 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shuber et al. (US Patent 5589330 December 31, 1996) in view of Wei et al. (Somatic Cell and Molecular Genetics Vol. 20 1994 p. 401) and Saiki et al. (WO 89/11548 November 30, 1989) as evidenced by Von Eggeling (Cellular and Molecular Biology .1995 Vol. 41 p. 653).

It is noted that Shuber et al. and Saiki et al. have been previously cited on an IDS and are found in the prosecution history.

The following rejection is being made based upon the indefiniteness of the determination of the percentage of RCG. It appears that in the specification degenerated primers with at least 8 nucleotide specificity will produce RCG of less than 1% or 0.05%. As such the following combination of art teaches a degenerate based primer that has a specific segment of 16 nucleotides. As such based upon the indefiniteness of the claim, such a primer would be encompassed by the claims.

With regard to Claim 151-152, Shuber et al. teaches a method of detection of genetic alterations in DNA samples (Abstract). Shuber et al. teaches a method in which single base differences can be resolved (e.g. SNP) (column 5 lines 24-25). Shuber et al. teaches a method of detecting the presence or absence of the allele (a SNP) (Column 11 lines 25-30).

Shuber et al. teaches a method in which human genomic DNA is fragmented by PCR amplification (column 2 lines 26-30 and column 4 lines 10-20). The instant specification defines RCG as "a reproducible fraction of an isolated genome which is composed of a plurality of DNA fragments" (p. 15 lines 23-25 of instant specification).

Further the instant specification describes RCGs as produced by PCR (p. 15 lines 30-31). Therefore a PCR derived fragment of DNA as taught by Shuber et al. would be encompassed by the definition provided. Therefore Shuber et al. teaches RCG that is PCR derived but does not teach that it is randomly prepared.

Shuber et al. teaches that ASO probes (e.g. allele specific oligonucleotides) are hybridized to RCGs (Figure 4 and column 6 lines 5-10). Shuber et al. teaches that the RCGs are immobilized to the solid support and the ASO probes are labeled. As such Shuber et al. teaches contacting a PCR derived RCG with SNP-ASOs. However, Shuber does not teach that the ASO probes are immobilized to the surface, but rather the RCGs are immobilized.

Shuber et al. teaches a method of determining rather the RCG is complementary to different mutant alleles comprised in the ASO probe by hybridization (column 6 lines 5-10 and figure 2A). Therefore Shuber teaches a method of hybridizing the RCG to the ASO to detect allelic differences.

Shuber et al. teaches that a plurality of RCGs from different patient samples can be compared and screened for particular mutations (Figure 4 and column 7 lines 50-60). The RCG in Shuber et al. is reproducible as the RCG is produced using a PCR methodology. As such depending on which RCG preparations are compared, these RCGs would have at least 50% of the same SNP-ASP sequences. Specifically if the RCG preparations are prepared so that the same genome is reproduced than the two RCG preparations would be identical and as such include at least 50% of the same SNP-ASO sequences (e.g. 100% of the same SNP-ASO sequences).

The specification states if "a reproducible fraction is produced twice or more using the same experimental conditions the fractions produced in each repetition include at least 50% of the same sequences....For instance, if a RCG is produced by PCR another RCG can be generated under identical experimental conditions having at a minimum greater than 90% of the sequences in the first RCG". Shuber uses PCR technology to produce the RCG. As such under identical experimental conditions the amplicons made by the combination of art would be capable of producing a reproducible fraction of the genome and capable of being prepared to include at least 50% of the same SNP-ASO sequences if two or more RCG preparations are compared to one another.

In summary, Shuber et al. teaches preparing a PCR derived reduced complexity genome using at least one PCR primer, contacting the RCG with SNP-ASOs, wherein polymorphic loci corresponding to the SNP-ASOs are present with a frequency of at least 50% in a RCG and determining the presence or absence of the SNP allele. However, Shuber does not teach that the RCG is randomly primed; that the RCG contains less than 20% of genomic material present in a whole genome, and that the SNP-ASOs are immobilized (rather in the case of Shuber the RCG is immobilized).

With regard to Claims 155-156, Shuber et al. teaches that the length of individual ASOs may be 16 to 25 nucleotides (column 4 lines 48-49).

Although Shuber et al. teaches a method of detecting ASOs in a sample, Shuber et al. does not teach that the sample is an RCG.

With regard to Claim 151-152, the art at the time of filing teaches production of RCGs. It appears that in the specification degenerated primers with at least 8 nucleotide specificity will produce RCG of less than 1% or 0.05%. Wei et al. teaches a degenerate based primer that has a specific segment of 16 nucleotides. Wei et al. teaches that a genomic sample was amplified using SIA PCR (p. 402 last full paragraph). Wei et al. teaches that this method uses two cycles in which the first cycle is a primer with 16 specific nucleotides at the 5' end and 6 degenerate nucleotides at the 3' end (p. 402 last paragraph). It appears that based upon the description in the specification and the lack of guidance to determine the calculation of RCG that having 16 specific nucleotides would produce a fragment of RCG that represents less than 0.05%. Wei et al. teaches that SIA derived DNA can be used to make region specific libraries for further analysis (p. 406 last paragraph). As such Wei With regard to Claims 151-152, Saiki et al. teaches a nucleic acid hybridization assay in which oligonucleotide probes (ASO probes) are attached to a solid support matrix (abstract). Saiki et al. teaches that preparation of immobilized probes can separate in time their use, allowing for the support to be used to rapidly detecting target nucleic acid sequences in test samples on demand (p. 9 lines 24-28).

With regard to Claim 53, Wei et al. teaches using SIA PCR, but does not specifically state that this is DOP PCR. However, as evidenced by Von Eggeling et al., SIA PCR is a nested DOP PCR system (p. 662 last paragraph).

The ordinary artisan would be motivated to modify the step of making the RCG taught by Shuber et al., because Wei et al. teaches that SIA derived DNA can be used

to make region specific libraries for further analysis (p. 406 last paragraph). As such the method of Wei et al. would suggest a fractionalization of the genome to be used for further analysis of a reduced portion of the genome. Therefore the ordinary artisan would use the PCR methodology taught by Wei et al. to produce fractionalization of the genome to be used in the high throughput genomic mapping of the method of Shuber et al. to screen for specific ASO alleles in reduced complexity genomes of the whole population to screen for specific alleles which may be found anywhere in a given genome.

The ordinary artisan would have been motivated to modify the method of Shuber et al. to immobilize the ASO oligonucleotides to the solid support instead of the taught method of immobilizing the RCG to the solid support in order to prepare arrays separately and be able to test different samples quickly on premade arrays of probes. Saiki et al. teaches that preparation of immobilized probes can separate in time their use, allowing for the support to be sued to rapidly detect target nucleic acid sequences in test samples on demand (p. 9 lines 24-28). As such the ordinary artisan would be motivated to prepare the solid supports ahead of time using the immobilization of the probe in order to produce a solid support which can be used on demand to rapidly detect SNPs in a target sequence.

9. Claims 151-152, 154-156 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shuber et al. (US Patent 5589330 December 31, 1996) in view of Guilfoye et al. (Nucleic Acids Research 1997 Vol. 25 p. 1854) and Saiki et al. (WO

89/11548 November 30, 1989).

It is noted that Shuber et al. and Saiki et al. have been previously cited on an IDS and are found in the prosecution history.

The following rejection is being made based upon the indefiniteness of the determination of the percentage of RCG. The specification teaches an adapter that has a 3 nucleotide overhang would yield a 64 fold reduction in complexity (p. 25 lines 2-15). As such a 6 nucleotide overhang would yield a 496 fold reduction in complexity (e.g. less than 0.05%).

With regard to Claim 151-152, Shuber et al. teaches a method of detection of genetic alterations in DNA samples (Abstract). Shuber et al. teaches a method in which single base differences can be resolved (e.g. SNP) (column 5 lines 24-25). Shuber et al. teaches a method of detecting the presence or absence of the allele (a SNP) (Column 11 lines 25-30).

Shuber et al. teaches a method in which human genomic DNA is fragmented by PCR amplification (column 2 lines 26-30 and column 4 lines 10-20). The instant specification defines RCG as "a reproducible fraction of an isolated genome which is composed of a plurality of DNA fragments" (p. 15 lines 23-25 of instant specification). Further the instant specification describes RCGs as produced by PCR (p. 15 lines 30-31). Therefore a PCR derived fragment of DNA as taught by Shuber et al. would be encompassed by the definition provided. Therefore Shuber et al. teaches RCG that is PCR derived but does not teach that it is randomly prepared.

Shuber et al. teaches that ASO probes (e.g. allele specific oligonucleotides) are hybridized to RCGs (Figure 4 and column 6 lines 5-10). Shuber et al. teaches that the RCGs are immobilized to the solid support and the ASO probes are labeled. As such Shuber et al. teaches contacting a PCR derived RCG with SNP-ASOs. However, Shuber does not teach that the ASO probes are immobilized to the surface, but rather the RCGs are immobilized.

Shuber et al. teaches a method of determining rather the RCG is complementary to different mutant alleles comprised in the ASO probe by hybridization (column 6 lines 5-10 and figure 2A). Therefore Shuber teaches a method of hybridizing the RCG to the ASO to detect allelic differences.

Shuber et al. teaches that a plurality of RCGs from different patient samples can be compared and screened for particular mutations (Figure 4 and column 7 lines 50-60). The RCG in Shuber et al. is reproducible as the RCG is produced using a PCR methodology. As such depending on which RCG preparations are compared, these RCGs would have at least 50% of the same SNP-ASP sequences. Specifically if the RCG preparations are prepared so that the same genome is reproduced than the two RCG preparations would be identical and as such include at least 50% of the same SNP-ASO sequences (e.g. 100% of the same SNP-ASO sequences).

The specification states if "a reproducible fraction is produced twice or more using the same experimental conditions the fractions produced in each repetition include at least 50% of the same sequences....For instance, if a RCG is produced by PCR another RCG can be generated under identical experimental conditions having at

a minimum greater than 90% of the sequences in the first RCG". Shuber uses PCR technology to produce the RCG. As such under identical experimental conditions the amplicons made by the combination of art would be capable of producing a reproducible fraction of the genome and capable of being prepared to include at least 50% of the same SNP-ASO sequences if two or more RCG preparations are compared to one another.

In summary, Shuber et al. teaches preparing a PCR derived reduced complexity genome using at least one PCR primer, contacting the RCG with SNP-ASOs, wherein polymorphic loci corresponding to the SNP-ASOs are present with a frequency of at least 50% in a RCG and determining the presence or absence of the SNP allele. However, Shuber does not teach that the RCG is randomly primed; that the RCG contains less than 20% of genomic material present in a whole genome, and that the SNP-ASOs are immobilized (rather in the case of Shuber the RCG is immobilized).

With regard to Claims 155-156, Shuber et al. teaches that the length of individual ASOs may be 16 to 25 nucleotides (column 4 lines 48-49).

However, Shuber et al. does not teach the production of RCGs.

With regard to Claim 151-152, the art at the time of filing teaches production of RCGs by using ligation mediated PCR (e.g. adapter-PCR). With regard to Claims 151-152 and Claim 154, Guilfoyle et al teaches a ligation mediated PCR (e.g. adapter PCR) in which overhangs of different length (2-5 bases) and polarity are created (p. 1854 2nd column 1st paragraph and Figure 1). Guilfoyle et al. teaches that a 6 cutter enzyme would cleave a random sequence every 4096 bp and will produce on average

244 fragments (p. 1872 1st paragraph). As such a 6 nucleotide overhang would yield a 496 fold reduction in complexity (e.g. less than 0.05%). Guilfoyle et al. teaches that this reduction in complexity approach can be used as a library of complex genomes so that replication is avoided (p. 1873 last paragraph). As such Guilfoyle et al. teaches a method of reducing the complexity of the genome so that a library can be made which can be used for other screening methods.

The ordinary artisan would be motivated to modify the step of making the RCG taught by Shuber et al., because Guilfoyle et al. teaches that this reduction in complexity approach can be used as a library of complex genomes so that replication is avoided (p. 1873 last paragraph). As such the method of Guilfoyle et al. would suggest a fractionalization of the genome to be used for further analysis of a reduced portion of the genome. Therefore the ordinary artisan would use the PCR methodology taught by Guilfoyle et al. to produce fractionalization of the genome to be used in the high throughput genomic mapping of the method of Shuber et al. to screen for specific ASO alleles in reduced complexity genomes of the whole population to screen for specific alleles which may be found anywhere in a given genome.

The ordinary artisan would have been motivated to modify the method of Shuber et al. to immobilize the ASO oligonucleotides to the solid support instead of the taught method of immobilizing the RCG to the solid support in order to prepare arrays separately and be able to test different samples quickly on premade arrays of probes. Saiki et al. teaches that preparation of immobilized probes can separate in time their use, allowing for the support to be used to rapidly detect target nucleic acid sequences

in test samples on demand (p. 9 lines 24-28). As such the ordinary artisan would be motivated to prepare the solid supports ahead of time using the immobilization of the probe in order to produce a solid support which can be used on demand to rapidly detect SNPs in a target sequence.

Conclusion

10. No claims are allowed.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE SALMON whose telephone number is (571)272-3316. The examiner can normally be reached on Monday - Friday 9AM-530PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Katherine Salmon/
Primary Examiner, Art Unit 1634

/Dave Nguyen/
SPE, Art Unit 1634

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